



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-21-21HI; Docket No. CDC-2021-0086]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC),
Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Red Carpet Entry (RCE) Program Implementation Project. This study will prepare for, implement, and evaluate an implementation model of linkage and reengagement to HIV care via a toolkit.

DATES: CDC must receive written comments on or before **[INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER]**.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2021-0086 by any of the following methods:

- Federal eRulemaking Portal: Regulations.gov. Follow the instructions for submitting comments.

- Mail: Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to Regulations.gov.

Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7118; E-mail: omb@cdc.gov.

SUPPLEMENTARY INFORMATION:

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection

before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected;
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses; and
5. Assess information collection costs.

Proposed Project

Red Carpet Entry (RCE) Program Implementation Project - New - National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

This project involves original, implementation research on the Red Carpet Entry (RCE) Program to link persons with HIV to care within 72 hours of their diagnosis or their return to care after being out of care. Originally developed and implemented in Washington D.C. by Whitman Walker Health and the D.C. Department of Health's HIV/AIDS, Hepatitis, STD, and TB Administration, Red Carpet Entry (RCE) has been shown to successfully and rapidly link people who tested HIV positive to an HIV care provider. Evaluations of RCE found that 70% of newly diagnosed people were linked to care within 72 hours of their HIV test. It was also shown to work for linking people who had fallen out of care with an HIV provider. An adapted version of RCE has also been shown to improve health outcomes among adolescents and youths in Kenya by quickly linking to care. The school-based program increased rates of linkage to care from 56.5% to 97.3% and three-month retention in care from 66.0% to 90.0%. Based on this, the CDC identified RCE as an evidence-informed structural intervention and included it in CDC's Compendium of Evidence-based Interventions (EBIs) and Best Practices for HIV Prevention.

Having an evidence-informed intervention like RCE that can be disseminated to the broader HIV health care community is important for several reasons: (1) antiretroviral therapy (ART) is the best way to manage HIV and reduce transmission; (2) ART initiation is only possible when someone enters health care and

then is ultimately retained in care; and (3) there are few existing evidenced-based structural interventions to support this process. This bias in the field of HIV interventions stems from a focus on individual behavior change interventions to prevent HIV infection. However, as new and effective treatments have emerged that reduce the likelihood of HIV transmission, HIV clinics and other healthcare settings have emerged as key contexts for HIV prevention by making sure that Persons with HIV (PWH) have immediate access to ART. Therefore, the field has slowly shifted to understanding how providers and health systems can be encouraged to support PWH to reduce HIV.

This study will contribute to the field by creating tools to support clinics and healthcare settings that want to implement the RCE Program to link PWH to care. A toolkit will be created and tested via implementing RCE in two clinics. Lessons from the implementation of RCE will be used to update the toolkit. The final toolkit will be disseminated via CDC's website. Furthermore, because the study also evaluates the implementation strategies, outcomes, and context when RCE is being used, the study will be able to recommend what is needed to implement RCE with fidelity and success and incorporate these insights into the toolkit. Finally, because tracking costs are also a part of the evaluation, clinics and health systems that are examining potential RCE adoption will have material information about what is needed to put RCE into practice. An

understanding of the actual costs can provide important justification for program planners.

The results of this study will help CDC frame how best to disseminate the RCE Program to the broader HIV health care community. This is important because only federal agencies like CDC have the resources and infrastructure to broadly disseminate EBIs. Broad dissemination and uptake of EBIs like RCE can help move population rates of HIV suppression which would affect population transmission rates. Linkage to care, in an era of biomedical HIV prevention, is a prevention linchpin. CDC requests approval for an estimated 125 annual burden hours. There are no costs to respondents other than their time.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses Per Respondent	Average Burden Per Response (in Hours)	Total Burden Hours
RCE Clients	Screeners	180	1	5/60	15
RCE Implementation Staff	Staff Survey - Preparation Phase	8	1	15/60	2
RCE Implementation Staff	Staff Survey - Implementation Phase (months 1,3,5)	8	3	15/60	6
RCE Implementation Staff	Staff Survey - Implementation Phase (months 2,4,6)	8	3	15/60	6
RCE Implementation Staff	Staff Interview Guide - Preparation Phase	8	1	1	8

Type of Respondents	Form Name	No. of Respondents	No. of Responses Per Respondent	Average Burden Per Response (in Hours) 30/60	Total Burden Hours
RCE Implementation Staff	Staff Interview Guide - Implementation Phase (months 1,3,5)	8	3	30/60	12
RCE Implementation Staff	Staff Interview Guide - Implementation Phase (months 2,4,6)	8	3	30/60	12
Clinic Leadership	Clinic Leadership Interview Guide	2	1	30/60	1
	Labor Cost Questionnaire	6	4	1.5	36
	Non-Labor Cost Questionnaire	2	9	1.5	27
Total					125

Jeffrey M. Zirger,

Lead,

Information Collection Review Office,

Office of Scientific Integrity,

Office of Science,

Centers for Disease Control and Prevention.

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